REMARKS

Claims 1 - 3, 6, and 7 currently pending. Claim 1 – 3 and 7 are amended herein and Claims 4, 5, and 8 – 17 are cancelled.

In the Office Action, the Examiner first objected to the Information Disclosure Statement (IDS) filed by the Applicants. On the merits, Claims 1 – 17 were rejected as allegedly failing to satisfy the utility requirement of Section 101. In addition, Claims 1 – 17 were rejected as allegedly failing to satisfy the enablement requirement of Section 112, first paragraph. Claims 16 – 17 were also rejected under Section 112, second paragraph as allegedly being indefinite. Finally, Claims 1 –5, 10, and 12 – 15 were rejected as allegedly being anticipated by U.S. Patent No. 6,764,997 to Tenengauzer et al. ("Tenengauzer").

Each of the objections and rejections set forth in the Office Action is respectfully traversed, and favorable reconsideration is requested in view of the amendments presented herein and following remarks.

The Objections to the IDS

Once again, the Examiner has objected to Applicants' IDS filed on October 7, 2005, on the alleged ground that it failed to comply with 37 CFR 1.98(a)(2) since copies of certain patent and non-patent documents listed on the IDS were allegedly not submitted to (or made available to) the Patent Office by way of the IDS.

While Applicants believe their submission of known information to the USPTO which may be deemed material to examination of this case is and was in substantial and complete compliance with their obligations under the rules, copies of the aforementioned documents are enclosed herewith, and it is requested that the Examiner withdraw the objection and consider the documents in the examination of this case.

The Utility Rejections

Turning to the claim rejections in the Office Action, the Examiner first contends that the claims fail to satisfy the utility requirement of Section 101 because, in her view, the claims are not supported by either a specific asserted utility or a well-established utility. It is submitted that these rejections are not well taken and should be withdrawn.

The claims of the present application are directed to novel derivatives of azithromycin, to pharmaceutical compositions comprising such derivatives of azithromycin, and to a process for making derivatives of azithromycin. It is unquestionable that azithromycin itself has a well-established utility as a pharmaceutical, sold commercially in the U.S. under the trade name Zithromax ® by Pfizer. It is reportedly the world's best selling antibiotic. Many derivatives of azithromycin are known and also have certain utilities, as is described in documents submitted with applicants' IDS. The utility of the azithromycin derivatives of Applicants' claims would likewise have been readily apparent to one of ordinary skill in the art after reading Applicants' specification.

On the very first page of Applicants' specification, it is stated that the basic antibiotic "[a]zithromycin (formula1) is a well-known antibacterial agent, described e. g. in the Merck Index, 13th edition (2001), page 159 (917)." As those of skill are well aware, azithromycin is a profoundly important antibiotic which may be used to treat a wide variety of bacterial infections such as middle ear infections, throat infections, and pneumonia, and sinusitis.

Applicants' specification further states that the "present invention relates to new derivatives of azithromycin, a process for preparing these new derivatives and *pharmaceutical compositions containing at least one new azithromycin derivative preferably together with azithromycin.*" (emphasis added). From this, one of ordinary skill would readily comprehend the new derivatives of azithromycin recited in Applicants' claims are useful in pharmaceutical compositions. More specifically, he or she would have recognized that the new derivatives of azithromycin could be used in a pharmaceutical composition, which is defined as composition containing "a medicinal drug." Thus, Applicants are explicitly asserting their azithromycin derivatives have utility at least as components of compositions containing a "medicinal drug." This is also confirmed by Claims 2 and 3, both of which recite a pharmaceutical composition including at least one of the new derivatives of azithromycin recited in Claim 1.

Further still, page 5 of Applicants' specification states that the "derivatives mentioned above are in form of a base or an acid addition salt, e. g. in the form of a *pharmaceutically acceptable salt*" (emphasis added) and page 10 discloses that "the present invention relates to *pharmaceutical compositions* comprising at least one new azithromycin derivative of formula 2,3, 4,6, 7 or 8, preferably together with any azithromycin salt or base in any crystalline, polymorphic or amorphous form." (emphasis added)

The Manual of Patent Examining Procedure (MPEP) instructs that a rejection based upon a lack of utility is improper and should not be imposed if a claimed invention has a "well-established utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible." *See* "Examination Guidelines for the Utility Requirement", MPEP § 2107. A lack of utility rejection is also improper if "the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art." In such a case, it is improper to impose a rejection based on lack of utility. *See* "Examination Guidelines for the Utility Requirement", MPEP § 2107. Applying these standards, the utility of the substance called for by the present claims is clearly established.

Based upon Applicants' disclosure, one of ordinary skill in the art would immediately appreciate that Applicants' novel derivatives of azithromycin may be used in pharmaceutical compositions and they are derivatives of an extremely and unquestionably well-known antibiotic. This utility asserted in the specification is specific, direct, substantial, and highly credible. With the release of cladinose per the examples, antibiotic activity to some degree similar to that of azithromycin would be expected by persons of ordinary skill according to established principles of medicinal chemistry. Thus, Applicants' claimed invention has a more than adequately established utility.

Moreover, Applicants' specification discloses a particular practical purpose for their novel derivatives of azithromycin, namely use as antibiotics in pharmaceutical composition, which is clearly credible to a person of ordinary skill in the art. Again, this credibility derives from chemical similarity of the derivatives to azithromycin and Applicants' specific disclosure that the derivatives may be used in antibiotics together with azithromycin, and that Applicants' derivatives yield cladinose and desosamine, thereby indicating antibiotic activity. Thus, Applicants' claimed invention has a specific asserted utility as well.

Accordingly, it is respectfully submitted that the Examiner's utility rejections of the pending claims are improper and should be withdrawn.

The Enablement Rejections

In addition to the lack of utility rejections discussed above, Claims 1 – 17 were also rejected under Section 112, first paragraph. The Examiner bases these rejections on the assertion that "since the claimed invention is not supported by either a specific asserted utility or a well established utility .... one skilled in the art clearly would not know how to use the claimed invention." Thus, the enablement rejections are dependant upon the Examiners' prior assertion that the invention defined in the claims lacks utility. Since this assertion has been refuted above, it is submitted that the enablement rejections of the currently pending claims are also improper and should be withdrawn.

The Indefiniteness Rejections

The Examiner also contends that Claims 16 and 17 are indefinite. Since Claims 16 and 17 have been cancelled by this amendment, these rejections are mooted.

The Prior Art Rejections

Finally, with respect to the prior art, the Examiner contends that Claims 1 –5, 10, and 12 – 15 are anticipated by the Tenengauzer patent. The Examiner's sole basis for this contention is a statement in the Background of Tenegauzer that

> Azithromycin is subject to degradation that can occur during manufacture and storage. In particular, the amine group of azithromycin is susceptible to oxidation. For example, azithromycin is susceptible to degradation if exposed to elevated temperatures and/or air during manufacturing processes, including processes of formulating pharmaceutical dosage forms of azithromycin.

See Col. 1, lines 34 – 40. Based upon this statement, the Examiner improperly speculates that "[s]ince the claimed azithromycin derivatives of formula 4, 6, and 7 are formed by oxidation of amine and the azithromycin derivative of formula 8 is formed by heating, said derivatives are seen to be inherently to be present as azithromycin degradation products during a manufacturing process."

It is first noted that since Claims 4, 5, 10, and 12 – 15 have been cancelled herein, the prior art rejections of these claims are now moot.

As for Claims 1 – 3, the azithromycin derivatives of formula 4, 6, 7 and 8 have been cancelled from Claim 1. Thus, the prior art rejections of Claim 1 and dependent Claims 2 and

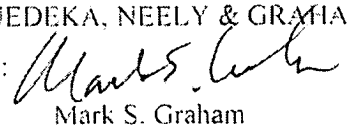
3 are also moot. Accordingly, it is submitted that all of the anticipation rejections based upon the Tenegauzer patent are now moot and should be withdrawn.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

LUEDEKA, NEELY & GRAHAM, P.C.

By: 

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